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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,127	10/05/2005	Petra Cirpus	12810-00136-US	6201
23416 7590 04/07/2008 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899				
EXAMINER MCILWAIN, ELIZABETH F				
ART UNIT 1638		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/552,127

Applicant(s)

CIRPUS ET AL.

Examiner

Elizabeth F. McElwain

Art Unit

1638

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/5/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date 10/05/11/21/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-3 and 5-16, in the reply filed on January 11, 2008 is acknowledged. The traversal is on the ground(s) that there is a general inventive concept of a novel delta-4 desaturase coding sequence and there would be no undue burden to search and examine all of the claims. This is not found persuasive because the inventions of Groups I-III do not share a special technical feature for the reasons set forth in the restriction requirement and it would be an undue burden to search and examine all three inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 1 is objected to for the recitation of "of" after "a)" at line 3.

Claims 10, 11, 14, 15 and 16 are objected to for the recitation of "where" instead of "wherein".

Claim 14 is objected to because there is no antecedent basis for "molecules" in claim 12.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3 and 5-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1, and claims 2, 3 and 5-16 dependent thereon, are indefinite in the recitation of the plural forms “polypeptides”, “sequences” and “derivates” in lines 1, 4, 6 and 7 of claim 1, given that the plural forms may encompass different sequences and/or portions of sequences.

Therefore, making the metes and bounds of the claims unclear.

5. Claim 1 is also indefinite in the recitation of “derivates”, which is not an art recognized term. The claim should be amended to recite “a derivative”, which is a term that is known in the art and is defined in the specification.

6. Claims 1, 6 and 7, and claims 2, 3, 5 and 8-16 dependent thereon, are indefinite in the use of improper Markush language, which must use closed language by reciting “selected from the group consisting of”.

7. Claim 12 is indefinite in that the claim is missing the step of producing polyunsaturated fatty acids prior to the step for recovering the polyunsaturated fatty acids.

8. Claim 12 is further indefinite and confusing in the use of the term “culturing” with regard to transgenic nonhuman organisms, given that the term culturing is typically used in the art for growing single-celled organisms or tissues, but not for whole multicellular organisms.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-3 and 5-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. The claims are drawn to a nucleic acid encoding a polypeptide having delta-4 desaturase activity, wherein the claims encompass any sequence that codes for a polypeptide having at least 40% homology at the amino acid level with SEQ ID NO: 2 and having a delta-4 desaturase activity. Claims also encompass said nucleic acid sequence in a vector and a transgenic nonhuman organism comprising said sequence and a process of producing polyunsaturated fatty acids by culturing the transgenic organism. However, the specification only discloses SEQ ID NO: 1 encoding SEQ ID NO: 2. The specification does not disclose other amino acid sequences that would have delta-4 desaturase activity and the specification does not disclose any specific structural features that define an amino acid sequence that has delta-4 desaturase activity.

"A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." In addition, "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention". See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions of nucleic acids encoding

delta-4 desaturases, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

12. Claims 1-3 and 5-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid sequence encoding SEQ ID NO: 2, and a transgenic yeast transformed therewith and a process of producing polyunsaturated fatty acids by transforming yeast with a construct comprising SEQ ID NO: 2, does not reasonably provide enablement for any nucleic acid sequence that encodes an amino acid sequence having delta-4 desaturase activity that has at least 40% homology with SEQ ID NO: 2, and for any gene construct comprising said sequence and a multitude of other genes for fatty acid biosynthesis or lipid metabolism, and for any nonhuman organism transformed with any of said sequences, and for producing polyunsaturated fatty acids with any of said sequences and in any nonhuman organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

13. The claims are drawn to a nucleic acid encoding a polypeptide having delta-4 desaturase activity, wherein the claims encompass any sequence that codes for a polypeptide having at least 40% homology at the amino acid level with SEQ ID NO: 2 and having a delta-4 desaturase activity. Claims also encompass said nucleic acid sequence in a vector and a transgenic nonhuman organism comprising said sequence and a process of producing polyunsaturated fatty acids by culturing the transgenic organism. However, the specification only exemplifies a nucleic acid encoding SEQ ID NO: 2 transformed into yeast that are fed with DPA for the production of polyunsaturated fatty acids, such as DHA. The specification discusses how to

transform a plant, but no plants are exemplified and no results with regard to fatty acid production are provided.

14. The specification teaches that the delta-4 desaturase from *Euglena* that is disclosed as SEQ ID NO: 2 is specific for conversion of DPA to DHA, and that the double bond at the C4-C5 position is only introduced when a double bond is already present at the C7-C8 position.

Therefore, the specification teaches that DPA must be present for use of the claimed delta-4 desaturase coding sequence. While the specification teaches transformed yeast that are grown in media supplemented with DPA, the specification does not teach any other organisms in which the claimed delta-4 desaturase will function or the culture conditions required for use of the claimed nucleic acid to produce polyunsaturated fatty acids. Nor does the specification teach how to use the claimed constructs comprising one or more nucleic acids encoding a polypeptide having at least 40% homology at the amino acid level with SEQ ID NO: 2 and further comprising any unspecified number of fatty acid biosynthetic genes or lipid metabolism genes that are listed in claims 6 or 7.

15. Given the recognition that use of the nucleic acid of the present invention is dependent on the presence of the appropriate fatty acid intermediates in an organism or culture medium, as discussed in the specification; and given the lack of guidance in the specification for use of sequences other than SEQ ID NO: 2 in organisms other than yeast cultured with DPA; and the absence of other working examples; and given the breadth of the claims, which encompass any nucleic acid encoding a polypeptide having at least 40% homology to SEQ ID NO: 2 and transformed into any nonhuman organism, and cloned into a vector further comprising a

multitude of other genes; it would require undue experimentation to make and/or use the invention, as broadly claimed.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 1-3 and 5-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Mukerji et al (WO 02/090493 in IDS).

19. The claims are drawn to a nucleic acid encoding a polypeptide having delta-4 desaturase activity, wherein the claims encompass any sequence that codes for a polypeptide having at least 40% homology at the amino acid level with SEQ ID NO: 2 and having a delta-4 desaturase activity, including a sequence derived from a plant, such as from the class of Euglenophyceae, wherein applicants define plants to include algae at page 20 of the specification. Claims also

encompass said nucleic acid sequence in a vector and associated with regulatory sequences, and a transgenic nonhuman organism comprising said sequence, and a process of producing polyunsaturated fatty acids, such as docosahexanoic acid (DHA) by culturing the transgenic organism. Claims are also drawn to said delta-4 desaturase coding sequence in a construct having additional biosynthesis genes of fatty acid or lipid metabolism, such as an elongase.

20. Mukerji et al teach several nucleic acid sequences encoding delta-4 desaturases, including that of the algae *Isochrysis* (page 11), and methods of isolating said nucleic acids. Mukerji et al also teach transforming host cells, animals and plants with a delta-4 desaturase coding sequence functionally connected to a regulatory sequence for the production of polyunsaturated fatty acids (PUFAs), such as DHA (see pages 9, 26-31, 54 and Figure 1, for example). Mukerji et al also teach transformation with additional genes, such as a fatty acid elongase (pages 52-53, for example).

21. Mukerji et al do not specifically teach a delta-4 desaturase that is at least 40% homologous to SEQ ID NO: 2. Mukerji et al also do not specifically teach multiple fatty acid biosynthetic genes cloned into one construct.

22. Given the recognition of those of ordinary skill in the art of the desirability of isolating delta-4 desaturase coding sequences from organisms, such as from an algal species, for the purpose of producing polyunsaturated fatty acids, such as DHA, in a transgenic organism, as taught by Mukerji et al, it would have been obvious to one of ordinary skill in the art to isolate other delta-4 desaturase coding sequences from other algal species, such as from *Euglena*. In addition, the transformation of other fatty acid biosynthetic genes on the same construct or on a different vector construct would be a matter of choice that would not confer patentable

distinction to the claimed invention. Thus the claimed invention would have been obvious as a whole at the time the invention was made, especially in the absence of evidence to the contrary.

23. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/
Primary Examiner, Art Unit 1638

